

**I. THE CLAIMS ARE PATENTABLE OVER U.S. PATENT NO. 5,599,305 TO HERMANN ET AL.**

Claims 115, and 117-123 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,599,305 to Hermann et al. (hereinafter "Hermann"). This rejection is respectfully traversed.

As amended, Claim 115 recites a method of repairing an aneurysm in a vessel using a sheath device having a housing with a first end portion and a second end portion. The method comprises the steps of: introducing the first end portion of the sheath device into the vessel such that the second end portion is positioned outside of the vessel; inserting a repair apparatus through an opening in the second end portion of the sheath device housing; removing the repair apparatus from the opening; and providing a sealing cavity for reducing the loss of blood from the vessel during the insertion and removal of the repair apparatus.

Hermann does not disclose, teach, or suggest the subject matter of the present invention. Hermann teaches a catheter introducer system for placement of a flexible sheath through the subclavian artery, across the aortic arch, and into the abdominal aorta. (Col. 11, lines 21-33 and 47-65; FIGS. 11A-11E). Hermann further discloses a delivery catheter that is advanced through the sheath, and a partial occlusion balloon that is expanded "in order to slow blood flow to the region of the aneurysm." *Id.* Hermann does not, however, suggest a method of repairing an aneurysm comprising the steps recited in the Claims of the present invention, including the step of providing a

sealing cavity for reducing the loss of blood from the vessel during the insertion and removal of the repair apparatus.

For at least the reasons set forth above, Applicants respectfully submit that Hermann fails to disclose, teach, or suggest the subject matter of the present invention. Reconsideration and withdraw of the rejection are respectfully requested.

**II. THE CLAIMS ARE PATENTABLE OVER HERMANN IN VIEW OF U.S. PATENT NO. 5,407,434 TO GROSS**

Claims 116, and 124-126 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hermann in view of U.S. Patent No. 5,407,434 to Gross (hereinafter "Gross"). This rejection is respectfully traversed.

As amended, Claim 124 recites a method of reducing the loss of blood from a vessel during the surgical repair of an aneurysm in the vessel using a sheath device having a housing with a first end portion, a second end portion, and a hollow interior that permits the passage of a repair apparatus, and a sealing cavity formed in the sheath device housing proximate to the second end portion. The method comprises the steps of: introducing the first end portion of the sheath device into the vessel proximate to the aneurysm such that the second end portion is positioned outside of the vessel; filling the sealing cavity with a self-sealing gel-like material adapted to permit the insertion and removal of the repair apparatus through the material and into the hollow interior while forming a seal around the repair apparatus; and reducing the loss of blood from the vessel during the surgical repair of the aneurysm.

As amended, Claim 126 recites a method of reducing the loss of blood during the surgical repair of an aneurysm in the abdominal aorta using a sheath device having a housing with a first end portion and a second end portion. The method comprises the steps of: introducing the first end portion of the sheath device to the abdominal aorta proximate to the aneurysm through an artery; inserting a repair apparatus through an opening in the second end portion of the sheath device housing; removing the repair apparatus from the opening in the second end portion of the sheath device housing; providing a sealing cavity formed in the sheath device housing proximate to the second end portion; filling the sealing cavity with a self-sealing gel-like material adapted to permit the insertion and removal of the repair apparatus through the material while forming a seal around the repair apparatus; and reducing the loss of blood during the surgical repair of the aneurysm.

Taken alone or in combination, neither Hermann nor Gross teach, disclose, or suggest the subject matter of the present invention. As discussed above, Hermann teaches a catheter introducer system for placement of a flexible sheath through the subclavian artery, across the aortic arch, and into the abdominal aorta. Hermann further discloses a delivery catheter that is advanced through the sheath, and a partial occlusion balloon that is expanded "in order to slow blood flow to the region of the aneurysm." (Col. 11, lines 21-33 and 47-65; FIGS. 11A-11E). Gross discloses a thoracentesis device which prevents air entry into the pleural cavity and lung puncture during use. Gross discloses a method of performing thoracentesis comprising the step of removing a needle from a patient after encounter with the pleural cavity, wherein

upon removal of the needle from the housing promotes formation of a viscous seal against the housing inner seat *so as to prevent the entrance of air into the pleural cavity*. (Col. 1, line 64 - Col. 2, line 8) (emphasis added). Hermann and Gross do not disclose, however, the subject matter claimed in the present invention.

Further, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine Hermann and/or Gross. First, the Examiner does not provide any authority in Hermann to combine with the device disclosed in Gross, and vice versa. Second, the two references are directed to entirely different medical fields. Hermann is directed to the treatment of aneurysms. Gross is directed to a thoracentesis device which is used in the removal of fluid from the pleural cavity. Third, there is not a reasonable expectation of success in the combination of Hermann and Gross. The partial occlusion balloon of Hermann would not be aided in the slowing of blood flow to the region of the aneurysm if provided with the housing disclosed in Gross.

For at least the reasons set forth above, Applicants respectfully submit that Hermann and Gross, taken alone or in combination, fail to disclose, teach, or suggest the subject matter of the present invention. Reconsideration and withdraw of the rejection are respectfully requested.

### **III. CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully submit that the Claims of the present invention define subject matter patentable over the references cited by the Examiner and that the application is in condition for allowance.

Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the below listed telephone number.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to deposit account number 03-2469. Moreover, if the deposit account contains insufficient funds, the Commissioner is hereby invited to contact Applicants' undersigned representative to arrange payment.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "J. Coulby", is written over a horizontal line.

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